K083009

FEB 19 2009

3.0 510(k) Summary

Device Trade Name:	Stryker Navigation System – OrthoMap® 3D Module
Common Name:	Navigation System
Product Code:	OLO
Classification Name:	Stereotaxic Instruments
Title 21 CFR:	§882.4560
Classification	II
510(k) Contact Person:	Lilian Eckert Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 D-79111 Freiburg Germany (+49) 761 45 12 117 email: lilian.eckert@stryker.com
Date Summary Prepared:	Feburary 9, 2009
Description:	The Stryker Navigation System – OrthoMap® 3D Module is part of the product series of the Stryker Navigation System. The system comprises software for surgical planning and computer assisted surgery based on a wireless optical tracking localization device for the use in navigated orthopedic oncology surgery.
Intended Use:	The Stryker Navigation System – OrthoMap® 3D Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified.
Indications:	The system should be operated only by trained personnel such as surgeons and clinic staff. The Stryker Navigation System – OrthoMap® 3D Module supports, but is not limited to, the following surgical procedures: **Orthopedic Oncology Procedures** *Surgical Planning Procedures* • Segmentation to define volumes of interest using correlated, multi-modality image data, e.g. to assist outlining and visualizing bony structures such as aberrant pathology • Image based distance and angular measurement tools, e.g. to define and maintain safety margins to outlined

bony structures
- Image based resection plane planning to define resections relative to identified structures, e.g. to support limb salvage surgery taking safety margins into account
- Virtual screw placement planning in the image data with variable screw length, head-length and diameter
- Image based annotation point placement and visualization, e.g. to support repositioning of bony anatomic points during surgery

Surgical Navigation Procedures

- Intra-operative visualization of volume image data including visualization of pre-planned volumes of interest relative to the tracked instrument, supporting navigated excision of user-defined bony structures
- Intra-operative visualization of resection planes relative to the tracked instrument on bony structures assisting bony resections
- Intra-operative creation and visualization of annotation points, supporting recording of landmarks on bony anatomy, e.g. to assist oncology replacement prosthesis repositioning, leg length and rotation assessment or navigated implant placement
- Navigated intra-operative screw placement based on pre-planned or intra-operative virtual screw definition

Equivalent to:	K062640 Cranial Module K012380 Spine & Fluoroscopy Module
Substantial Equivalence:	The Stryker Navigation System – OrthoMap® 3D Module does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System – OrthoMap® 3D Module is substantially equivalent to these existing devices. They will be designed and manufactured in accordance with Stryker Leibinger's Quality Management System covered by QSR 21CFR 820.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Leibinger GmbH & Co.,KG
% Ms. Lilian Eckert
Regulatory Affairs Specialist
Bötzinger Straße 41
D-79111 Freiburg
Germany

FEB 19 2009

Re: K083009
Trade/Device Name: Stryker Navigation System – OrthoMap® 3D Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: February 10, 2009
Received: February 13, 2009

Dear Ms. Eckert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David Krause

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(K) Number (if known): K083009

Device Name: Stryker Navigation System – OrthoMap® 3D Module

Intended Use

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Indications for Use

The system should be operated only by trained personnel such as surgeons and clinic staff.
The Stryker Navigation System – OrthoMap® 3D Module supports, but is not limited to, the following surgical procedures:

Orthopedic Oncology Procedures

Surgical Planning Procedures

- Segmentation to define volumes of interest using correlated, multi-modality image data, e.g. to assist outlining and visualizing bony structures such as aberrant pathology
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- Image based resection plane planning to define resections relative to identified structures, e.g. to support limb salvage surgery taking safety margins into account
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(K) Number K083009

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083009